` PUBLIC HEALTH REGULATIONS
DEPARTMENT OF HEALTH, STATE OF HAWAII

Chapter 30

CLINICAL LABORATORIES, CLINICAL LABORATORY DIRECTORS AND OTHER CLINICAL LABORATORY TECHNICAL PERSONNEL

Under the provisions of Section 321-11(12) and 321.13, Hawaii Revised Statutes, and all other applicable laws, Chapter 30 of the Public Health Regulations of the Department of Health is hereby amended to read as follows:

Section 1. Definitions

1-A. In this chapter, unless the context otherwise requires:

1. "Person" means any individual, firm, association, corporation, municipality, political subdivision, or any other entity whether organized for profit or not.

2. "Department" means the State Department of Health.

3. "Director of Health" or "Director" means the Director of the State Department of Health.

4. "Clinical laboratory" means any institution, building or place in which operations or procedures for the microbiological, serological, chemical, hematological, immunohematological, biophysical, toxocological, cytological, or pathological examinations of specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment. This will include a blood bank.

5. "Laboratory acceptable to the Department" means any clinical laboratory licensed by the Department or licensed by another state whose requirements are equal to or higher than Hawaii's; any public health laboratory operated by a municipal, state or federal government; any clinical laboratory which has been approved in accordance with the Clinical Laboratories Improvement Act of 1967 and its Regulation or the "Conditions for Coverage of Services of Independent Laboratories" under Medicare.

6. "Clinical laboratory owner" means a person or agency in whom is vested the rights of control, possession, and dominion of a clinical laboratory, and for the purposes of these regulations shall include the state, a county, municipality, or any other owner of an institution operating a clinical laboratory.

7. "Clinical laboratory director" or "laboratory director" means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results.

8. “Clinical laboratory supervisor” means a person who, under the general supervision of a clinical laboratory director, supervises the technical personnel, and performs tests requiring special scientific skills.

9. “Clinical laboratory technologist” or “clinical laboratory specialist” or “cytotechnologist” means a person who performs tests which require the exercise of independent judgment and responsibility, with minimal supervision by the clinical laboratory director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training, and experience.

10. “Clinical laboratory technician” means a person who functions only under the supervision of a clinical laboratory director, supervisor, technologist, or specialist and performs clinical laboratory procedures only in those specialties or subspecialties in which he is qualified.

11. “Clinical laboratory assistant” means a person who functions only under the direct and personal supervision of a clinical laboratory director, supervisor, technologist, or specialist and performs only those clinical laboratory procedures which require limited technical skill, responsibility, and a minimal exercise of independent judgment.

12. “Clinical laboratory trainee” means any person having qualifying education who is employed in a clinical laboratory approved for training and who is seeking experience required to meet minimum qualifications for licensure in the State. Trainees may perform clinical laboratory procedures under direct and responsible supervision of a clinical laboratory director, supervisor, technologist, or specialist.

13. “Clinical laboratory evaluation program” means a program operated or approved by the Department for evaluating the proficiency of clinical laboratories.

14. “A clinical laboratory advisory committee” shall mean a group of consultants appointed by the Director of Health to advise the Department on matters relating to the regulation of clinical laboratories.

15. “Collecting depot” means a place separate from patient care facilities where specimens are received or taken from the body of an individual for laboratory examination elsewhere.

Section 2. Application and Exemptions

2-A. This Chapter applies to all clinical laboratories and clinical laboratory personnel within the State of Hawaii, except:

1. A clinical laboratory operated by the United States Government.

2. A clinical laboratory operated and maintained exclusively for research and teaching purposes, involving no patient or public health services whatsoever.

3. A clinical laboratory operated by one or several physicians performing diagnostic tests solely for his or their own patients. However, such a clinical laboratory shall be required to comply with Section 4.J of this Chapter and may be required to demonstrate proficiency.

4. Police Department of any county and its personnel performing breath alcohol analysis by instrumentation.

5. Any study of public health importance having the written approval of the Director.

Section 3. Clinical Laboratory Licensure

3-A. No person shall establish conduct, or maintain a clinical laboratory in this State, or engage in the business of providing clinical laboratory services to persons within the State, unless a license, therefore, has been obtained from the Department.

3-B. No clinical laboratory licensed under this Chapter shall send specimens for examination to any laboratory whose principal place of business is outside the State of Hawaii unless such laboratory has been approved by and registered with the Department as meeting the minimum standards for clinical laboratories as provided by this Chapter. When specimens have been referred for examination to an out-of-state laboratory, the report shall bear or be accompanied by a clear statement that such findings were obtained in such other laboratory and shall specify its name and location.

3-C. A person who desires to operate a clinical laboratory shall file with the Department an application on a form prescribed and furnished by the Department. The application shall contain:

1. The name and location of the clinical laboratory.
2. The name of the person owning such facility and the name of the person directing such facility.
3. A description of the program and services provided by such clinical laboratory.
4. Such other information as the Department may deem necessary or expedient in carrying out its powers and duties under this Chapter.

3-D. The Department shall issue a license to the applicant to operate a clinical laboratory to provide the programs and services described in the application if the Department is satisfied that there is a clinical laboratory director in charge who is the holder of a license issued pursuant to Section 8-B and that the person who supervises tests and those who perform tests comply with Section 8-C, 8-D, 8-E or 8-F. Laboratory trainees may be employed if they serve under the immediate supervision of a licensed clinical Laboratory director, supervisor, technologist, or specialist and the number of trainees does not exceed one half the number of such licensed personnel in such laboratory.

3-E. A clinical laboratory license shall be effective for a period of twelve (12) months and shall be renewable annually on its anniversary date.

3-F. When inspection, investigation or proficiency testing of a clinical laboratory reveals a deficiency or deficiencies of a minor nature but the Director has cause to believe that the immediate interests of the general public would be best served by affording the clinical laboratory the opportunity to correct such deficiency or deficiencies, the Department shall issue a provisional license for a period of time not to exceed six (6) months providing the applicant agrees to carry out a plan acceptable to the Department to eliminate the deficiency or deficiencies within the term of the provisional license. No provisional license shall be renewed. A clinical laboratory shall be re-licensed after the expiration of its provisional license only if the applicant has fully corrected all conditions constituting failure to comply with requirements for licensure.

3-G. A license to conduct a clinical laboratory where the owner is not the clinical laboratory director shall be issued to the owner, but the owner and clinical laboratory director shall be severally and jointly responsible to the Department for the maintenance and conduct thereof, or for any violations of the provisions of this Chapter. A separate license shall be obtained for each location. A license shall be valid only in the hands of the persons to whom it is issued and shall not

be the subject of sale, assignment, or transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which issued. A new license may be secured for a new location, clinical laboratory director, or owner prior to the actual change, provided that the contemplated change is in compliance with the provisions of this Chapter, and that the Department has had thirty days' notice of the contemplated change.

3-H. The license of a clinical laboratory shall state the specialties and subspecialties which the clinical laboratory is authorized to perform. A clinical laboratory shall perform only those tests that are within the specialties or subspecialties stated on its license. The license shall include only those specialties or subspecialties which the clinical laboratory director or technical personnel are qualified to perform. The clinical laboratory director shall notify the Department in writing of any additions/deletions of specialties or subspecialties within ninety (90) days after the change has been effected. Specialties shall be designated as follows:

1. Microbiology, including the subspecialties of bacteriology, virology, mycology and parasitology.
2. Serology, including the subspecialties of syphilis serology and nonsyphilis serology.
3. Clinical Chemistry, including the subspecialties of routine blood and cerebrospinal fluid chemistry, endocrinology, toxicology, urinanalysis, and other chemistry.
4. Hematology.
5. Immunohematology, including the subspecialties of blood grouping and Rh typing, Rh antibody titers, compatibility testing and others.
6. Pathology, including the subspecialties of diagnostic cytology, histopathology and oral pathology.
7. Radiobioassay.
8. Tests not included in any of the above specialties, or such other procedures as the Department may specify.

3-I. No license shall include the specialty of tissue pathology and or exfoliative cytology unless tissue specimens or specimens for cytologic examinations are to be examined on the premises by a pathologist or a physician who in the opinion of the Department is qualified by training and experience to perform such procedures.

3-J. Licensure shall imply approval of the location and supervision of such clinical laboratory and shall serve as notice to the Department of the character of the program and services performed. A clinical laboratory shall not in any advertisement, announcement, letter, circular, poster, sign, or in any other manner include any statement expressly or by implication to the effect that it is approved by the Department except as provided by paragraph 3-K of this Section.

3-K. A person who maintains, conducts, or operates a clinical laboratory shall display in a prominent place in the clinical laboratory the license issued to him by the Department.

Section 4. Physical Facilities and Procedures

4-A. No license shall be issued a clinical laboratory unless the clinical laboratory premises and the equipment used therein has been approved by the Department as adequate for the proper performance of the type of tests the clinical laboratory is authorized to perform. This shall include the plumbing, heating, cooling, lighting, ventilation, refrigeration, electrical services, sanitary conditions and adequate fire protection within the clinical laboratory and its surroundings, and the water supply, sewage disposal and handling and disposal of specimens; and proper safety measures for personnel.

4-B. No establishment other than a clinical laboratory or a collecting depot conducted in conformity with Section 5 shall receive specimens for the purpose of obtaining information for

diagnosis, prevention or treatment of a disease or the assessment of a medical condition. This subsection shall not be deemed to prohibit the acceptance of specimens solely for teaching purposes.

4-C. Except as otherwise provided in subsection 4-E of this Section, a clinical laboratory shall examine specimens only at the request of a licensed physician or other person authorized by law to use the findings of laboratory examinations in his or her practice. If the request is oral, the physician or other authorized person shall submit a written request to the clinical laboratory within forty-eight (48) hours. If the clinical laboratory does not receive the written request within that period, it shall note that fact in the record of daily accession of specimens as required by Section 7-B.

4-D. The result of a test shall be reported directly to the licensed physician or other authorized person who requested it. Upon written request of a patient, the result of a test may also be sent to any other licensed physician or other authorized person designated by the patient. No diagnosis or prognosis or suggested treatment shall be part of the laboratory report, except that reports made by a licensed physician may include such information when such reports are signed by the physician.

4-E. All specimens accepted by a clinical laboratory for specified tests shall be tested on its premises. However, specimens for infrequently performed tests or those not included within specialties or subspecialties stated on its permit, or those requiring specialized equipment and skill, may be forwarded to and accepted by another laboratory licensed by the Department or licensed for interstate commerce or a laboratory which is operated by a governmental agency or a nonprofit research institution or to any other laboratory approved by the Department. The reports of the results of such tests shall be sent by the testing laboratory to the forwarding clinical laboratory, and the forwarding clinical laboratory shall send a transcript of such reports to the physician or other authorized person who requested the tests and shall indicate thereon the name of the laboratory in which the test was actually performed.

4-F. No person other than a licensed physician or one otherwise authorized by law shall manipulate a patient for the collection of specimens, except that licensed and/or registered clinical laboratory personnel as described in Section 8-B, 8-C, 8-D, 8-E, and 8-F(a) and (b) of a clinical laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction of or upon the written request of a licensed physician.

4-G. Syringes, needles, lancets or other blood letting devices capable of transmitting infection from one person to another shall not reused unless they are heat sterilized prior to each use, provided that they have been wrapped or covered in a manner which will insure that they will remain sterile until the next use. Heat sterilization shall be:

1. By autoclave at 121_C. (250_F) at fifteen (15) pounds of steam pressure for not less than thirty (30) minutes after the chamber of the autoclave has been evacuated of air and has reached such temperature, or
2. By dry heat for two (2) hours at 170_C. (338_F), or
3. By other methods approved in writing by the Department.

4-H. Prior to disposal all possibly contaminated items such as blood clots, sera, culture media, and syringes and needles that have been made inoperable, etc. shall be decontaminated.

4-I. No clinical laboratory shall advertise its laboratory services to the general public. Advertising directly to practitioners of the healing arts through brochures or leaflets or in reputable professional publications or business directories is permissible if it does not contain misleading

statements or claims of unusual superiority.

4-J. The clinical laboratory director of a clinical laboratory shall report to the Department all laboratory findings which indicate the presumptive presence of any disease required to be reported in Chapter 5. Public Health Regulations (Communicable Diseases), or as required by other statutes or regulations.

4-K. When requested a clinical laboratory shall submit reports containing such information and data concerning its technical operation as may be specified by the Department. Such reports shall be signed by both the owner and clinical laboratory director of the clinical laboratory.

Section 5. Collecting Depot

5-A. A clinical laboratory may maintain collecting depots after first obtaining written approval from the Department for the establishment of each such depot.

5-B. A collecting depot shall:

1. Have to be approved by the Department as adequate for the proper collection of specimens. This shall include the staffing, plumbing, heating, cooling, lighting, ventilation, refrigeration, electrical services, sanitary conditions and adequate fire protection within the collecting depot and its surroundings, and the water supply, sewage disposal and handling and disposal of specimens; and the proper safety measures for personnel. Heat labile specimens will be kept refrigerated until removal for delivery to a clinical laboratory for testing.

2. Have a record indicating the daily accession of specimens containing the following information:

(a) The name, initials or other identification and address of the person from whom the specimen was taken.

(b) The name and address of the licensed physician or other authorized individual who requested the test.

(c) The date and hour when the specimen was received or when it was collected.

(d) The type of test requested.

5-C. No tests shall be performed in a collecting depot.

Section 6. Specimens: Identification and Examination

6-A. Every properly labeled specimen received for testing shall be numbered or other wise appropriately identified and listed in an accession book, or otherwise listed in chronological order.

6-B. Every tissue specimen, other than a specimen for exfoliative cytology, shall be examined and reported upon by a qualified pathologist who is certified or eligible for certification for pathologic anatomy by the American Board of Pathology or a physician whose qualifications, in the opinion of the Department, are the equivalent of such certification.

6-C. Every specimen for exfoliative cytology, shall be reported upon by a qualified pathologist who is certified or eligible for certification by the American Board of Pathology, or a physician who, in the opionion of the Department is qualified by training and experience to perform such procedures.

Initial examinination or “screening” of specimens for exfoliative cytology may be made by a person who is qualified as a licensed clinical laboratory cytotechnologist or by a person who has special training in cytology acceptable to the Department.

6-D. A clinical laboratory shall at any time during its regular working hours permit the inspection of its premises, records, incubators, material and equipment by a representative of the Department and shall, for the purpose of determining its competence, examine all specimens

submitted by the Department in the presence of a representative thereof and shall report promptly the results of such examination to the Department.

In lieu of inspections by the Department, inspections and accreditation by the College of American Pathologist, Joint Commission on Accreditation of Hospitals, Medicare, CLIA-67 (CDC),

National Institutes of Health or other inspecting and accrediting agencies approved by the Department will be recognized as fulfilling this requirement.

6-E. If the component to be tested for in a specimen is perishable, labile or otherwise subject to deterioration, such specimen shall be tested as promptly as possible after collection. If a specimen is transported or stored, it shall be properly preserved, refrigerated, frozen, or otherwise appropriately treated to maintain it in as close to its original state as is possible by then current techniques.

6-F. A specimen received by a clinical laboratory shall not be tested or reported on if:

1. The apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested.
2. It has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen.
3. It is perishable and the time lapse between the collection of the specimen and its receipt by the clinical laboratory is of such duration that the test finding may no longer be reliable.
4. The date and, in the case of tests specified by the Department, the hour when the specimen was taken by the physician or other authorized person are not furnished with specimen.

6-G. When a specimen is not tested for any of the reasons specified in Section 6-F of this Section, the clinical laboratory shall promptly notify the sender and give the reason therefor.

6-H. All technical procedures employed in a clinical laboratory shall be standard procedures which are generally accepted by authorities in the specialties of laboratory medicine or which are otherwise approved by the Department.

Section 7. Records

7-A. Each clinical laboratory shall retain a duplicate copy of the original report made to the physician or other authorized person of each specimen received for analysis.

7-B. Each clinical laboratory shall have a record indicating the daily accession of specimens and containing the following information:

1. The laboratory number or other identification of each specimen.
2. The name, the initials or other identification of the person from whom the specimen was taken.
3. The name of the licensed physician or other authorized person or clinical laboratory who submitted the specimen.
4. If the request for the test was oral and not followed by a request as required by Section 4-E a statement to that effect.
5. The date, and hour if required, the specimen was collected.
6. The date, and hour if required, the specimen was received in the clinical laboratory.
7. When the specimen is forwarded to another laboratory for tests, the name, the date when the specimen was forwarded to such laboratory, the date it was tested and the date the report of the findings of the tests was received from such laboratory.
8. The condition of unsatisfactory specimens when received (e.g. broken, leaked, hemolyzed or turbid, etc.).

9. The type of test performed.

10. The result of the laboratory test or cross reference to results.

11. The date a report was sent to the Department pursuant to Section 4-K of these regulation.

12. The name, the initials or other identification of the person who performed each test, or, in the case of a test involving performance by more than one person, the name, the initials or other identification of the persons who actually supervised the test on site.

7-C. All records and reports of test performed, including the original or duplicates of original reports from another laboratory, shall be kept on the premises of both laboratories and shall be exhibited to representatives of the Department on request. All such records and reports shall be retained for at lease five (5) years.

7-D. Each clinical laboratory shall:

1. Maintain current personnel records either in the clinical laboratory or personnel office. These records shall include a resume of the employee's training and experience, including dates of previous and current employment.

2. Submit lists of clinical laboratory personnel with their technical qualifications to the Department of Health on an annual basis. The Director of Health shall be notified within 90 days of changes in technical personnel.

Section 8. Clinical Laboratory Personnel Licensed, Qualifications, Duties and Examination

8-A. No person shall serve as a clinical laboratory director, supervisor, technologist, specialist, cytotechnologist or technician except under a valid and effective license issued to him by the Department.

8-B. Clinical laboratory director

1. Every clinical laboratory shall be under the direction of a clinical laboratory director who must meet one of the following qualifications:

(a) Be a physician, licensed to practice medicine in the State of Hawaii, who is certified by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for such certification (board eligible).

(b) Be a physician, licensed to practice medicine in the State of Hawaii.

(c) Having (i) a doctoral degree from a college or university recognized by the National Commission on Accrediting, or one that is otherwise acceptable to the Department in the fields of chemical science, physical science, biological science, or public health, (ii) been certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Department in one of the clinical laboratory specialties, (iii) had (2) years of pertinent experience in one or more of the clinical laboratory specialties in a laboratory acceptable to the Department, (iv) satisfied the Department of his or her special qualifications in the specific areas of clinical laboratory testing for which licensure is sought.

(d) Have (i) a master's degree from a college or university recognized by the National Commission on Accrediting or one that is otherwise acceptable to the Department in medical technology, microbiology, chemistry or biology, (iii) satisfied the Department of his or her special qualifications in the specific areas of clinical laboratory testing for which licensure is sought.

(e) Have (i) a bachelor's degree from a college or university recognized by the National Commission on accrediting, or one that is otherwise acceptable to the Department in medical technology, microbiology, chemistry or biology, (ii) had a minimum of (6) years of pertinent experience in a laboratory acceptable to the Department, and (iii) satisfied the Department of his or

her special qualifications in the specific areas of clinical laboratory testing for which licensure is sought.

2. In addition, a clinical laboratory director qualifying under (c), (d), or (e) above, must pass an oral, written and or practical qualifying examination, in general, laboratory science and in the specific areas of laboratory testing for which licensure is sought.

3. A person who on the effective date of these regulations was a licensed clinical laboratory director of an established clinical laboratory may continue to direct such laboratory, but may not assume directorship of any other clinical laboratory unless specifically authorized to do so by the Department.

4. The clinical labortory director shall be responsible for the proper performance of all tests made in the clinical labortory. He or she shall be responsible for the employment of laboratory personnel who are qualified under Section 8-C, 8-D, 8-E, or 8-F of these regulations. The clinical laboratory director shall spend an adequate amount of time, commensurate with the laboratory workload, in the active direction of the clinical laboratory.

5. A person shall not be permitted to direct or supervise more than three (3) clinical laboratories.

6. No more than one person shall serve as clinical laboratory director of any clinical laboratory. The clinical laboratory director may designate an employee of the clinical laboratory who holds a clinical laboratory director's or supervisor's license to be an associate clinical laboratory director to assist him or her in the technical operation of the clinical laboratory.

7. If the clinical laboratory director is temporarily absent for more than two (2) weeks but not more than two (2) months, the associate clinical laboratory director, if any, or if there be none, a person whose qualifications are satisfactory to the Department and who has been approved by the Department prior to his or her appointment, may direct the clinical laboratory. If the clinical laboratory director is to be absent for more than two (2) months but not more than one (1) year, a qualified substitute clinical laboratory director shall be employed unless there has been in the employ of the clinical laboratory an associate clinical laboratory director. In either event, the owner shall notify the Department that such substitute or associate clinical laboratory director will act as the clinical laboratory director.

8. When a clinical laboratory director's employment is terminated, for whatever cause, the owner and or the clinical laboratory director shall notify the Department within fourteen (14) days.

8-C. Clinical laboratory supervisor.

1. A clinical laboratory supervisor must meet one of the following qualifications:

(a) Have (i) a doctoral degree from a college or university recognized by the National Commission on Accrediting, or one that is otherwise acceptable to the Department in the fields of chemical science, physical science, biological science, or public health, (ii) had a minimum of one (1) year of pertinent experience one or more of the clinical laboratory specialties in a laboratory acceptable to the Department, (iii) satisfied the Department of his or her special qualifications in the specific areas of clinical laboratory testing for which licensure is sought.

(b) Have (i) a master's degree from a college or university recognized by the National Commission on Accrediting, or one that is otherwise acceptable to the Department in medical technology, microbiology, chemistry or biology, (ii) had a minimum of two (2) years pertinent experience in one or more of the clinical laboratory specialties in a laboratory acceptable to the Department , (iii) satisfied the Department of his or her special qualifications in the specific

areas of laboratory testing for which licensure is sought.

(c) Have (i) a bachelor's degree from a college or university recognized by the National Commission on Accrediting, or one that is otherwise acceptable to the Department in medical technology, microbiology, chemistry or biology, (ii) had a minimum of three (3) years pertinent experience in one or more of the clinical laboratory specialties in a laboratory acceptable to the Department, (iii) satisfied the Department of his or her special qualifications in the specific areas of laboratory testing for which licensure is sought.

2. In addition, a clinical laboratory supervisor must pass an oral, written, and or practical qualifying examination in one or more of the clinical laboratory specialties. On the recommendation of the Clinical Laboratory Advisory Committee, qualifying examinations may be waived by the Department for persons with unusual backgrounds or proven ability.

3. A person may supervise only in those areas of specialty for which he or she has been licensed.

8-D. Clinical laboratory technologists clinical laboratory specialists, cytotechnologists.

1. Clinical laboratory technologist or clinical laboratory specialist.

A clinical laboratory technologist or clinical laboratory specialist must meet one of the following qualifications:

(a) Have a bachelor's degree from a college or university recognized by the National Commission on Accrediting, or one that is otherwise acceptable to the Department in medical technology and successfully completed one (1) year training as a medical technologist trainee in a program approved by the Council on Medical Education of the American Medical Association.

(b) Have successfully completed three (3) academic years of study (a minimum of ninety (90) semester hours) in a college or university recognized by the National Commission on Accrediting, or one that is otherwise acceptable to the Department which meets the specific requirements for entrance into, and the successful completion of a course of training in a school of medical technology approved by the Council on Medical Education of the American Medical Association.

(c) Have (i) a bachelor's degree from a college or university recognized by the National Commission on Accrediting or one that is otherwise acceptable to the Department in one of the chemical, physical or biological sciences, (ii) had a minimum of one (1) year of pertinent laboratory experience and/or training covering the specialty(ies) or subspecialty(ies) in which he performs test, provided the combination has given the individual the equivalent in such specialty(ies) or subspecialty(ies) of the education and training described in subparagraph (a) or (b) of this paragraph, (iii) satisfied the Department of his or her special qualifications in the specific areas of laboratory testing for which licensure is sought.

(d) Have (i) successfully completed three (3) years (a minimum of ninety (90) semester hours) from a college or university recognized by the National Commission on Accrediting, or one that is otherwise acceptable to the Department in one of the chemical, physical or biological sciences, (ii) had one (1) year of pertinent laboratory experience and/or training covering several fields of medical laboratory work, and of such quality that this experience or training, when combined with the education, will have provided the individual with education and training in medical technology equivalent to that described in subparagraph (a) or (b) of this paragraph, (iii) satisfied the Department of his or her special qualifications in the specific areas of laboratory testing for which licensure is sought.

(Distribution of course work: where semester hours are stated, it is understood that the equivalent in quarter hours is equally acceptable. The specified courses must have included lecture

and laboratory work where applicable).

(i) For those whose training was completed prior to September 15, 1963: at least 24 semester hours in chemistry and biology courses of which not less than 9 semester hours must have been in chemistry and must have included at least 6 semester hours in inorganic chemistry, and not less than 12 semester hours must have been in biology courses pertinent to the medical sciences.

(ii) For those whose training was completed after September 15, 1963: 16 semester hours in chemistry courses which included at least 6 semester hours in inorganic chemistry and are acceptable toward a major in chemistry: 16 hours in biology courses which are pertinent to the

medical sciences and are acceptable toward a major in the biological sciences; and 3 semester hours of college level mathematics.

2. Cytotechnologist.

A cytotechnologist must meet one of the following qualifications:

(a) Have successfully completed two years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences and must have received 12 months in a school of cytotechnology approved by the Council on Medical Education of the American Medical Association.

(b) Have successfully completed two years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences and must have received 6 months of formal training in a school of cytotechnology approved by the Council on Medical Education of the American Medical Association and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training.

(c) For those trained prior to January 1, 1969, he or she must have graduated from high school, completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology and completed two (2) years of full-time experience in cytotechnology.

3. In addition, a clinical laboratory technologist, specialist, or cytotechnologist must pass an oral, written, and or practical qualifying examination in one or more of the clinical laboratory specialties. On the recommendation of the Clinical Laboratory Advisory Committee, qualifying examinations must be waived by the Department for persons with unusual backgrounds or proven ability.

4. A clinical laboratory technologist, specialist, or cytotechnologist may perform in each specialty or subspecialty included in his or her state license, tests which required the exercise of independent judgment and responsibility with minimum supervision, and in addition may supervise the work of technicians, assistants and trainees. With respect to specialties not included in his or

her license, the clinical laboratory technologist may function only under direct supervision and perform only tests which require limited technical skill and responsibility.

5. Until January 1, 1978, technical personnel who do not meet the educational requirements as stated for clinical laboratory technologist or clinical laboratory specialist and entotechnologist may be licensed as such provided they meet all of the following requirements.

(a) Graduation from a high school.

(b) Five (5) years experience at the technician level in a laboratory with a director at the doctoral level of which two (2) years must have been just prior to the application date. For persons who attended a university or college, 30 semester hours of college course work (of which at least six (6) semester hours must have been in one of the physical, chemical, or biological sciences, and

three (3) semester hours of college level mathematics) may be substituted for one (1) year experience.

(c) Has been supported by a letter of recommendation by the applicant's laboratory director.

(d) Has successfully passed an equivalency or proficiency examination approved by the Department.

8-E. Clinical laboratory technician.

1. A clinical laboratory technician must meet one of the following requirements:

(a) Have an associate's degree from a recognized college or university by the National Commission on Accrediting, or one that is otherwise acceptable to the Department.

(b) Have (i) successfully completed sixty (60) semester hours at a college or university recognized by the National Commission on Accrediting or one that is otherwise acceptable to the Department with at least twelve (12) semester hours in chemistry, bacteriology, or parasitology courses and three (3) semester hours in college level mathematics, (ii) had a minimum of six (6) months of full-time training or experience as a clinical laboratory technician in a laboratory acceptable to the Department. Three (3) months of the training or experience must have been within two (2) years prior to the application date.

(Distribution of course work: where semester hours are stated, it is understood that the equivalent in quarter hours is equally acceptable. The specified courses must have included lecture and laboratory work where applicable.)

(c) Have (i) graduated from a high school, successfully completed a medical technicians training course of not less than one (1) year as approved by the Council of Medical Education and Hospitals of the American Medical Association; or successfully completed a medical technician training program of not less than one (1) year as approved by the Accrediting Bureau of Medical Laboratory Schools or by the International Society of Clinical Laboratory Technologist Accrediting Commission: or successfully completed an official military laboratory training course of not less than fifty (50) weeks; (ii) had a minimum of one (1) year of pertinent full-time experience as a clinical laboratory technician or trainee in a laboratory acceptable to the Department. Six (6) months of the one (1) year experience must have been within two (2) years prior to the application date.

(d) Have (i) graduated from a high school, (ii) successfully completed a training course as a clinical, laboratory assistant, (iii) had a minimum of three (3) years of progressive pertinent full-time experience as a clinical laboratory assistant in a laboratory acceptable to the Department (one (1) year of the three (3) years experience must have been just prior to the application date), (iv) be recommended by the applicant's clinical laboratory director.

(i) After January 1, 1978 a clinical laboratory technician qualifying under (c) and (d) above must successfully pass an equivalency examination to meet the formal education requirements.

2. In addition a clinical laboratory technician must pass an oral, written, and/or practical qualifying examination in one or more of the laboratory specialties. On the recommendation of the Clinical Laboratory Advisory Committee, qualifying examinations may be waived by the Department for persons with unusual backgrounds or proven ability.

3. A technician may function only under the supervision of a clinical laboratory director, supervisor, technologist, or specialist. He or she may perform laboratory procedures only in those specialties or subspecialties in which he or she is qualified.

8-F. Other clinical laboratory technical personnel.

1. The following categories of clinical laboratory personnel do not require a license, but must be registered by the clinical laboratory director with the Department:

(a) Clinical laboratory assistant.

A clinical laboratory assistant must meet the following requirement:

(i) Graduation from a high school and have pertinent full-time experience in a laboratory acceptable to the Department of not less than one (1) year.

(b) Clinical laboratory trainee.

A clinical laboratory trainee must meet one of the following requirements:

(i) Be a person in a recognized medical technology, clinical laboratory specialist or clinical laboratory cytotechnologist training program as referred to in Section 8-D above.

(ii) Be a person in a recognized medical technician training course as referred to in Section 8-E above.

(iii) Be a person in a recognized medical laboratory assistant training course as referred to in Section 8-F(a) above.

2. A person shall serve as a clinical laboratory trainee for no longer than two (2) years. However, such period may be extended for persons who, for reasons deemed sufficient by the Department, have not been able within the two (2) year period to qualify as a clinical laboratory technologist technician or assistant.

3. A clinical laboratory assistant or trainee may function only under the personal and direct supervision of a clinical laboratory, supervisor, technologist or specialist. He or she may perform clinical laboratory procedures only in those specialties or subspecialties in which he is qualified by virtue of his education and training and only those procedures which require limited technical skill and responsibility and a minimal exercise of independent judgement.

4. No one with lesser qualifications than a clinical laboratory trainee may perform laboratory procedures, although housekeeping and clerical supplemental services may be rendered by others.

5. No clinical laboratory assistant or trainee may perform tests in the absence of a qualified clinical laboratory director, supervisor, technologist or specialist.

8-G. Exemptions.

1. Clinical laboratory directors and technologists who present satisfactory proof that they were licensed as such in the State of Hawaii on the date of approval of these regulations and are deemed qualified by the Clinical Laboratory Advisory Committee, shall be issued licenses without examination by the Department if they apply before January 1, 1976.

8-H. Notification of Examinations.

1. Thirty (30) days prior to an examination date a notice of examination shall be sent to all clinical laboratories and other institutions, organizations or individuals who have expressed an interest in the examination. Such notice shall include date, place, and minimum passing grade.

Section 9. Revocation or Suspension of License

9-A. A license to act as a clinical laboratory director, supervisor, technologist, or technician under Section 8-B, 8-C, 8-D, or 8-E may be revoked or suspended for one or more of the following reasons:

1. A false statement made on an application for a license or on any other document required by the Department.

2. Dishonest reporting or permitting dishonest reporting.

3. Conviction of a felony or any crime involving moral turpitude under the laws of any State of the United States or of the Federal Government. The record of conviction or a certified copy

thereof shall be conclusive evidence of such convictions.

4. The adjudication of insanity or mental illness.

5. Knowingly permitting unauthorized persons to perform technical clinical laboratory procedures or issue or sign reports.

6. Consistent error in the results of tests performed, supervised or directed by the person holding such license or having such authority.

7. Knowingly performing a test and rendering a report thereon to a person not authorized by law to submit the specimen.

8. Any other cause which the Director of Health deems detrimental to the public health.

9-B. The Director of Health shall suspend the license of a clinical laboratory director, supervisor, technologist, or technician, or the authority of a person to perform, supervise, or direct the performance of tests in one or more specialties or subspecialties, for a period not exceeding thirty (30) days, pending the final determination of charges against such a person, whenever there has been error in the results of tests performed by him or under his supervision to such a degree that, in the opinion of the Director of Health, health and or life may be endangered.

9-C. A license of a clinical laboratory under this Chapter may be revoked or suspended for one or more of the following reasons:

1. A false statement made on an application for a license or any other document required by the Department.

2. Knowingly permitting unauthorized persons to perform technical procedures or issue or sign reports.

3. Consistent error in performance of laboratory procedures, based on faulty technique or controls.

4. Dishonest reporting.

5. Knowingly performing a test and rendering a report thereon to a person not authorized by law to submit the specimens.

6. Failure to make a report of a communicable disease pursuant to Section 4-K of this Code.

7. Any other cause which the Director seems detrimental to the public health.

9-D. The Director of Health shall suspend the license of a clinical laboratory to perform tests within one or more specialties or subspecialties stated on a license, for a period not exceeding thirty (30) days, pending the final determination of charges against the licensee, whenever there has been error in performance to such a degree that in the opinion of the Director of Health, health and/or life may be endangered.

9-E. All actions under this section shall be taken pursuant to Chapter 91, Hawaii Revised Statutes.

Section 10. Fees

10-A. The following fees shall be collected by the Department for the initial licensure of clinical laboratory personnel, and for the annual renewal of licenses. All licenses shall expire on the 31st day of January each year.

		Initial	**Renewal**
(a)	Clinical Laboratory Directors	$25	$5
(b)	Clinical Laboratory Supervisors	10	3
(c)	Clinical Laboratory Technologists or Specialists . . .	10	3
(d)	Clinical Laboratory Technicians	10	3

10-B. Any person holding a license under the provisions of this chapter, who fails, neglects

or refuses to re-register or to pay the re-registration fee, after thirty (30) days of delinquency, shall forfeit his license. The license shall be restored upon written application with the Department together with payment of all delinquent fees and a sum equal to the fee for the original license. If such delinquency continues for more than one year, such person shall submit to and successfully pass an examination to be conducted by the Department before such license is restored.

10-C. Where examination materials are purchased from a professional organization or examination service, the Department may charge the applicant for the cost of such material. Such charges are to be over and above the fees listed above.

Section 11. Proficiency Testing and Quality Assurance Programs

11-A. The Department may require the demonstration of proficiency in the performance of the tests offered by the clinical laboratory by means of State-operated or State-approved proficiency testing programs such as College of American Pathologist, American Association of Bioanalysts, CLIA-67 (CDC) or other programs approved by the Department.

11-B. The use of State-operated or State-approved proficiency testing programs will be determined by the Director of Health and when State-approved programs are used, the cost must be borne by the clinical laboratory.

11-C. Standards of acceptable proficiency will be established for each category of specimens submitted by the proficiency testing program. A clinical laboratory will be required to display and maintain proficiency in each of the specialties or subspecialties for which it is licensed.

11-D. Renewal of licensure may be denied for failure to maintain an acceptable standard of proficiency in the program and services provided by a clinical laboratory.

11-E. There shall be an adequate quality assurance program in effect, including the use, where applicable, of reference or control sera and other biological samples, concurrent calibrating standards, and control charts recording standard readings.

11-F. There shall be a program of preventative maintenance and periodic inspection or testing for proper operation of equipment and instruments, with records of such maintenance, inspection and or testing. This shall include the monitoring of all temperature controlled instruments and equipment.

11-G. Current procedural manuals or card files shall be maintained in the clinical laboratory and all reagents or solutions shall be properly identified as to content, titer, strength, concentration, recommended storage, preparation or expiration date, and other pertinent information.

Section 12. Clinical Laboratory Advisory Committee

12-A. A Clinical Laboratory Advisory Committee of seven (7) members serving without pay and electing their chairman, shall be appointed by the Director of Health from persons who are specially trained in but not limited to one or more of the following disciplines: medicine, pathology, medical technology, bacteriology, serology, virology, chemistry, cytology, histology, immunohematology, mycology, and parasitology. The Chief of the Laboratories Branch of the State Department of Health shall be a member and permanent executive secretary of the Committee.

12-B. The Committee shall meet at least quarterly and or on call of any three members of the Committee. They shall advise the Director on the administration and enforcement of these regulations, review and recommend on licensure of clinical laboratories and clinical laboratory personnel, and evaluate and recommend programs for clinical laboratory improvement.

An agenda of the meeting shall be circulated at least one week prior to each meeting, and the Executive Secretary or his representative shall attend each meeting.

The unexcused absence of any Committee member for three consecutive meeting shall be grounds for his replacement on the Committee by the Department of Health.

12 C. The Clinical Laboratory Advisory Committee shall consist of representatives of the following organizations: One (1) member from the Department of Health; two (2) members from the Hawaii Medical Association; two (2) members from the Hawaii Society of Pathologists; and two (2) members from the Hawaii Society for Medical Technologists. Each organization shall nominate one (1) representative and one (1) alternate to serve on the committee. In making the appointments, the Director shall take into consideration the nominations made by the various professional organizations.

12-D. Initially, the Committee shall consist of two (2) members appointed for a three (3) year term, two (2) members appointed for a two (2) year term, and two (2) members appointed for a one (1) year term. Thereafter appointments will be for three (3) year terms and no member, other than the Executive Secretary, will be eligible to immediately succeed himself after he has served two (2) consecutive terms.

Section 13. Penalties

13-A. Any person who violates these Regulations shall be fined not more than five hundred (500) dollars or imprisoned not more than one (1) year, or both.

Section 14. Constitutionality Clause

14-A. Should any Section, paragraph, sentence, clause phrase or application of this chapter be declared unconstitutional or invalid for any reason, the remainder of this chapter shall not be affected thereby.

14-B. Every provision of this chapter shall be liberally construed to protect the interests of all persons affected.